

3 2 3 9 '98 OCT 27 P4 '50

October 7, 1998



Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW Washington, DC 20204

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) Name and address of manufacturer:
  Pharmavite Corporation, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):

Populations that consume large amounts of soy in their daily diets often have good bone health. Soy 50 provides you with 50 mg of soy isoflavones (the active components of soy), an amount equivalent to that contained in 2 oz. of pure soy. With Soy 50 you can get many of the benefits of soy without changing your regular diet.

- (3) Name of the dietary ingredient if not provided in the text of the statement: see above
- (4) Name of the dietary supplement:
  products containing soy isoflavones as a single ingredient or in combination with
  other ingredients

The above statement(s) may be used in one or more of the following brands of products: Nature Made, Sunny Maid, Nature's Resource, AAFES, AARP, Osco, Sav-On, Valu Wise, Bartell Drug, CVS, Duane Reade, Walgreens, Longs, Spring Valley, Brite Life, Family Pharmacy, GNP, Valu-Rite.

4 = T 2330



We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,

David Kropp

Manager, Regulatory and Legal Affairs

DK:ecb/soy 50.doc